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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/519,188 03/06/00 WONG

P PH-7038

EXAMINER

HM22/0510

DU PONT PHARMACEUTICALS COMPANY  
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KIM, V

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

05/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

<b>Office Action Summary</b>	<b>Application N</b> 09/519,188	<b>Applicant(s)</b> WONG, PANCRAS C.	
	<b>Examiner</b> Vickie Y. Kim	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 20) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 provides for the use of the claimed composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b/e) as being anticipated by Pruitt et al (US 6,060,491) or Dominguez et al (US 5,886,191).

The claims read on a method of treating thrombosis in a mammal comprising :  
administering a therapeutically effective amount of a combination of (i) a Factor Xa inhibitor, and (ii) a compound selected from aspirin, TPA, a GPIIb/IIIa antagonist, low molecular weight heparin and heparin, wherein the dose administered for at least one of (i) and (ii) is a subtherapeutic dose due to synergistic effect.

US'491 teaches all the critical elements required by the instant claims. First the patented reference teaches a pharmaceutical composition a inhibitor of factor Xa, alone or in combination with other therapeutic agents to prevent or ameliorate the thromboembolic diseases condition or the progression. The said other therapeutic agents include anti-coagulant such as aspirin(preferred) , platelet inhibitory agent such as Iib/IIIa antagonists, thrombin inhibitors such as heparins, or thrombolytic or fibrinolytic agents such as TPA; see column 119, lines 55 to column 121, lines 10. It also teaches that the said combination results additive or synergistic activity wherein typical daily dosage may be reduced; see column 124, lines 3-43. All the critical elements are taught by this patented reference. Thus the claimed subject matter is not patentably distinct over the prior art.

US'191 also teaches all the critical elements required by the instant claims; see abstract and columns ; columns 80-84.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Pruitt et al (US 6,060,491) or Dominguez et al (US 5,886,191) in view of Ewing et al (US 5,612,353).

Pruitt et al or Dominguez et al's teaching is mentioned immediately above.

Applicant's claim differs because they require a low molecular weight heparin.

However it would have been obvious to one of ordinary skill in the art to substitute a low molecular weight heparin to therapeutic agents(e.g. heparin:thrombolytic agent) taught in those cited references of Pruitt or Dominguez.

Ewing et al teach a combination therapy of Factor Xa and a low molecular weight heparin and it's greater antithrombotic efficacy or thrombolytic efficacy; see column 33, lines 52-60.

One would have motivated to extend by Pruitt et al (US 6,060,491) or Dominguez et al (US 5,886,191)'s teaching to include a low molecular weight heparin because a low molecular weight heparin is also effective as well as others wherein enhanced efficacy with lower side effects and safety.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar)

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ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

***Conclusion***

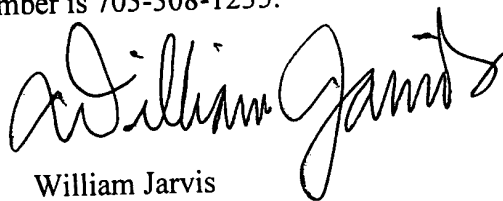
7. All the pending claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
April 24, 2001



William Jarvis  
Primary examiner  
Art unit 1614